K113831

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APR 19 2012

Chapter 5 510(k) Summary

510(k) Information

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92(a)

Submitter/Owner

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Summary date: March 08, 2012

Device Identification

Submission type: Traditional
Reason for Submission: New Device
Trade name: Primus Fitting System
Common name: Primus
Classification name: Hearing aid calibrator and analysis system
Secondary class: Audiometer, 21 CFR 874.1050, EWO
FDA: 21 CFR 874.3310
Device Product Code: ETW
Classification Panel: Ear, Nose, and Throat
Device Class: Class II

Predicate Marked Device

Primus Fitting System has equivalence to:

Product Name: Aurical
Manufacturer: GN Otometrics
510(k) Number: K945199

Device Description

The Primus Fitting System is a PC operated system that contains Primus Hearing Instrument Test unit (PHITU) for Hearing Instrument testing (HIT), Primus Fitting Unit (PFU) for Audiometry (AUD) and Real Ear measurement (REM). The Primus Fitting System is operated from a dedicated software application installed on a standard Windows operating system. The Primus Fitting system can either be sold individually (PHITU or PFU) or together (PHITU and PFU).

The Primus software solution operates within the NOAH framework, as well as stand-alone. On-top diagrams and control panels make it easy to use simultaneously with the proprietary hearing instrument fitting systems of your choice. The stand-alone client data files hold all historical session information, and makes fittings away from the office very easy.

Audiometry (AUD)
Primus AUD is a PC based audiometry module providing a wide range of possibilities within pure tone audiometry, bone conduction audiometry and speech audiometry including inserts probe and industry standard headsets with an option of high frequency testing.

Real Ear Measurements (REM)
Primus REM offers classic Real Ear Measurements as well as comprehensive Speech Mapping measurements, where all measurements include high frequency testing. The measurements are supported by a large sound library including technical sounds, daily life sounds, speech signals and dialogue. The Primus REM module contains 2 probes (one for each ear) each with 2 microphones used for measuring the sound level outside and inside the ear.

The classic Real Ear Measurements, which can be performed by Primus REM, include: Unaided, Occluded and Aided Response as well as Insertion Gain. Toggling between SPL and Gain shows the response measurements in gain view.

The PFU hardware is powered by a USB connection from the PC and a medical grade power supply (for extended sound pressure) and can be placed at the most convenient working place.

Hearing Instrument Testing (HIT)
Primus HIT offers full featured technical measurements for testing and troubleshooting hearing instruments. The test can be run as an automatic test sequence in accordance with European and American standards. The Primus HIT unit module contains of 2 microphones (one for measuring and one for reference) and various couplers for hearing aid testing.

The PHITU hardware is powered by a USB connection from the PC and can be placed at the most convenient working place.

PHITU Indication for Use/Intended use

Indications for use (PHITU):

The Primus Hearing Instrument Test Unit is intended for use by professionals such as an audiologist, hearing healthcare specialist, or trained technician.
Audiometric testing should take place in an extremely quiet environment and care should be taken to ensure optimal test conditions and safety of the client during testing.

The Primus Hearing Instrument Test Unit is intended to give an objective indication of the characteristics of a Hearing Aid, by visualizing a signal recorded in the test coupler with reference information such as target curves in order to make adjustments of the Hearing Instrument settings.

- The Primus Hearing Instrument Test Unit is indicated for technical quality inspection of hearing instruments with no clients involved.

Indications for use (PFU):

The Primus Fitting Unit is intended for use by professionals such as an audiologist, hearing healthcare specialist, or trained technician.
Audiometric testing should take place in an extremely quiet environment and care should be taken to ensure optimal test conditions and safety of the client during testing.

- The Primus Fitting Unit is intended for hearing test.
- The Primus Fitting Unit with stated accessories is indicated for non-continuous, noninvasive air and optionally bone conduction and speech audiometric testing in quiet office and sound treated environments.
- The Primus Fitting Unit is indicated for non-continuous real-ear measurements at the ear drum by means of noninvasive external ear canal insertion of a probe tube in quiet office environments.
- Finally the system can be used to present hearing instrument related sound examples through headsets or loudspeakers.
- The Primus Fitting Unit is indicated for use with both pediatric and adult age groups.
- The Primus Fitting Unit is not indicated as a sole means of diagnostics.

Technological Characteristics

The PHITU and PFU unit uses the same overall technology as the predicate devices:

PFU/PHITU	Predicate devices
Conventional electronic circuit board design	Similar design
Industry standard Digital Signal processor	Similar design
Conventional molded plastic parts design	Similar design
Conventional sheet metal design	Similar design
Industry standard headset	Same
Mains operated energy source	Same

Comparison to Predicate Device

Fitting systems like the Primus Fitting System have been produced for decades. The system most similar to the Primus Fitting System in terms of technical design and features is the Aurical from GN Otometrics.
From a measurement perspective, the two systems utilize very similar signal processing and electrical design within the device, and both are controlled and operated by software running on the PC.
The primary difference between the two devices is associated with the mechanical design, where Aurical is a combined AUD/REM/HIT unit and Primus Fitting System have independent HIT and REM/AUD unit operated by software running on the PC.

Substantial Equivalence Performance testing

Substantial equivalence to the Primus Fitting system is based a side-by-side design comparison (Aurical from GN Otometrics K945199) all verified by means of non-clinical performance testing of the Primus Fitting system as specified in ANSI S3.6, ANSI S3.22 and ANSI S3.46
This is further supported by the design implementations obtained as a result being compliant to the standards listed below.

Conclusion about Safety and Effectiveness

Evaluating the results of testing to the following key standards has allowed us to make conclusions about the safety and effectiveness of the Primus Fitting System.

Standard	Description
EN/IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety.
EN/IEC 60601-1- 2	Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests
ANSI/ S3.22	Specification of Hearing Aid Characteristics
IEC 60118-7	Electroacoustics - Hearing aids - Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes
EN60645-1/ANSI S3.6 Type 1	Tone Audiometry
EN60645-2/ANSI S3.6 Type A or A-E	Speech Audiometry
EN 61669	Equipment for the measurement of real-ear acoustical characteristics of hearing aids.
ANSI S3.46	Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids

The equivalent results from both the Primus fitting System and the Aurical System obtained when each device was tested to determine compliance with the standards clearly demonstrates the substantial equivalence between these two devices.

Based on the results of testing to the applicable requirements of the aforementioned standards and achieving compliance to them, we hereby conclude that Primus Fitting System is both safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Auditdata A/S
c/o Mr. Dan Haugbol
Banestroeget 13
DK-2630 Taastrup
Denmark

APR 19 2012

Re: K113831
Trade/Device Name: Primus Fitting System
Regulation Number: 21 CFR 874.3310
Regulation Name: Hearing aid calibrator and analysis system
Regulatory Class: II
Product Code: ETW, EWO
Dated: March 8, 2012
Received: March 14, 2012

Dear Mr. Haugbol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113831

Indications for Use Statement

510(k) Number: K113831
Device Name: Primus Fitting System

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113831

Prescription Use X
(Per 21 CFR 801.109)